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K962317

MAY - 7 1997

510(k) Summary

This 510(k) Summary is being submitted pursuant to the requirement of 21 CF 807.92(c).

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Date prepared: April 23, 1996

2. Device trade name: Magnetic Encephalograph
Proprietary name: Magnes 2500 WH biomagnetometer

3. Substantial equivalence is claimed to the Magnes II biomagnetometer, manufactured and marketed by Biomagnetic Technologies, Inc. (Reference 510(k) K941553)

4. Description of Device: The Magnes 2500 WH biomagnetometer (hereafter "Magnes 2500 WH") comprises a magnetic sensor for detecting and measuring the magnetic fields produced by the human brain, along with the auxiliary equipment required to perform the measurements in a conventional medical facility environment and to display the results of the measurements to physicians in a variety of ways.

The sensor utilizes an array of superconducting magnetic field pickup coils arranged in such a manner as to sense the magnetic fields over the portion of the skull enclosing the brain. For each such coil, a superconducting quantum interference device (SQUID) is used to detect the current induced in that coil by the brain magnetic field and produce a voltage proportional to the magnetic flux change. Conventional electronic and computer circuitry is used to amplify, filter, digitize, store and display the result of the measurement. The sensor includes an insulated reservoir of liquid helium as a refrigerant for cooling the superconducting components - pickup coils, SQUIDs, and interconnecting leads - to temperatures below their superconducting transition temperature. Heat is conducted from these superconducting elements along thermally conductive pathways into the helium reservoir.

Provided as part of the Magnes 2500 WH biomagnetometer are the following ancillary items:

Magnetically shielded room, comprised primarily of nickel-rich alloy and aluminum sheeting, to provide shielding from environmental sources of magnetic or rf noise

Manually operated non-magnetic gantry to place the sensor over the head of the patient in either a seated or supine position

Non-magnetic patient table with hydraulic elevation, to support the patient securely in either seated or supine position

Non-magnetic patient monitoring and communication devices, including video monitor, intercom, and head motion detector

Head shape and head position measurement system, to provide head shape and location relative to the sensor for data modeling and display

Computer workstation, operator console, and software to control system operation, data acquisition and storage, and data analysis and display

Sensory stimulus systems, to provide stimulation of the patient's somatosensory, auditory, visual, and motor systems for magnetic measurement of evoked response

Results of the measurement of magnetic fields produced by the brain are available in tabular form and may be visualized as waveforms, contour maps of lines of equal magnetic field values, and as equivalent single current dipoles.

5. Intended Use: The Magnes 2500 WH is intended for use in diagnostic procedures that require the measurement and display of extracranial magnetic fields and information about the electrical activity in the brain as inferred from those fields.

6. Technological Characteristics: The Magnes 2500 WH operates with the same principles of operation as the predicate device, the Magnes II biomagnetometer. Magnetic field changes induce currents in superconducting pickup coils, those currents are detected and converted to voltages by superconducting quantum interference devices or SQUIDs, and those voltages are amplified, filtered, digitized, stored, analyzed and displayed for use by a physician. The primary technological difference between the Magnes II and the Magnes 2500 WH is that the latter features 148 pickup coils distributed over the entire surface of the skull overlying cortical tissue while the former features two arrays of 37 pickup coils, each covering a circular area approximately 15 cm in diameter.

Because the cryogenic container housing the pickup coils is by necessity rigid and head sizes and shapes vary from patient to patient, the distance from some of the pickup coils to the skull of a patient may be greater than with the Magnes II. To compensate for this, the pickup coils are constructed as magnetometers rather than axial gradiometers as in the Magnes II. Magnetometer coils offer greater sensitivity to brain sources of magnetic fields than gradiometer coils but at the expense of greater sensitivity to extrinsic magnetic noise. A secondary set of pickup coils, spatially separated from the primary pickup coils, are used to detect magnetic noise and subtract it from the primary signals, creating the functional equivalent of an axial gradiometer.

The Magnes II refrigerates one set of the superconducting components of the sensor by immersing them directly in liquid helium, the other by solid thermal conduction. In the Magnes 2500 WH, all of the superconducting components are refrigerated by solid thermal conductors which thermally connect each such component to the liquid helium reservoir.

In the Magnes II, the position of the patient's head was measured using a third-party position indicator system which operated by essentially measuring the mutual inductance between small receiver coils mounted on the patient's head or in a wand and a low level rf transmitter coil mounted on one sensor housing. In the Magnes 2500 WH, the same principle of operation is employed, but small very low level transmitter coils are mounted on the patient's head and the field produced by those coils is measured by the biomagnetometer pickup coils themselves.

7. Non-clinical tests: The substantial equivalence between the Magnes II and Magnes 2500 WH was verified by comparative non-clinical tests of each of the technological characteristics which are different, as described in 6) above.

To demonstrate the substantial equivalence of the magnetometer pickup coils as used in the Magnes 2500 WH to the gradiometer coils as used in the Magnes II, two bench tests were run. In the first, a dipolar source in a head phantom was activated and measured with each of the sensors, both in the normal ambient environment of the factory and in the presence of artificially produced magnetic noise. The spectral content of the waveform as measured with each sensor were then compared for both conditions. The waveforms showed no significant difference from each other, in either operating condition.

As a second test of this characteristic, the dipole in the head phantom was localized using the Magnes II and Magnes 2500 WH sensors in a number of trials. There was no significant difference for any of the dipole parameters between the two sensors - physical location, strength, or orientation.

To demonstrate the substantial equivalence of the method of refrigeration, the magnetic field produced by a fixed source was detected by representative pickup coils in the Magnes 2500 WH when the helium level in the reservoir was full and when it was nearly empty. A similar test was conducted with the upper sensor of a Magnes II, in which the direct immersion method of refrigeration is used. Sensitivity of the various channels was compared for these two operating conditions and no material difference measured.

Finally, to demonstrate the substantial equivalence of the methods of measuring head position, repetitive measurements of the location of reference points on a head phantom were conducted with the positioning system in the Magnes II and with the new approach taken in the Magnes 2500 WH. No significant difference between the relative locations of the reference points was found.

8. Conclusion: The comparative non-clinical tests produced no significant differences between those elements of the Magnes II and the correspondent elements of the Magnes 2500 WH for which there has been some change in technological approach. Since all other elements of the two systems are technologically the same, we conclude that the Magnes 2500 WH is substantially equivalent to the predicate Magnes system.

Please direct any questions concerning this 510(k) Summary to the contact person noted above.